



Ralston Purina
Company

Environmental Assessment for the Addition of 0.3 ppm Selenium to Swine
Prestarter and Starter Rations

1. Date: June 1, 1981
2. Name of Applicant/Petitioner: Ralston Purina Company
3. Address: Checkerboard Square
St. Louis, MO 63188
4. Description of the Proposed Action:

Ralston Purina Company has petitioned the Food and Drug Administration (FDA) to amend 21 CFR, Section 573.920(b)(2) to provide for the use of the food additive selenium in swine prestarter and starter rations at a level not to exceed 0.3 ppm in complete feed. Selenium is currently approved for use at a level not to exceed 0.1 ppm in complete swine feeds.

Weanling swine up to the grower stage need greater concentrations of selenium than do older swine. This greater need in the post-weaning period occurs because of the rapid depletion of selenium and Vitamin E from swine tissues hastened by weaning stress. The rate of depletion is influenced by the tissue reservoir of this nutrient in the weaning pig. Faster growing pigs have a greater selenium nutritional requirement than slower growing ones, hence, unless the nutritional factors provide for this enhanced growth, death may result. Since the 1974 approval for the use of selenium at .1 ppm in swine diets, selenium deficiencies in starter pigs have continued in certain geographical areas. The 1974 .1 ppm selenium approval for swine was based upon data demonstrating a need for .1 ppm added selenium for growing and finishing swine but did not contain data on prestarter or starter swine. It is now apparent that a higher level of added selenium (0.3 ppm) is needed to meet weaning pigs selenium needs.

Approval of this request will result in only a minimal increase in total use of supplemental selenium. The potential environmental effect will likewise be minimal and insignificant. To evaluate the environmental effects of adding .3 ppm selenium to complete prestarter and starter rations on a worst-case basis, we have determined that each pig will consume 5 pounds of complete prestarting ration and 60 pounds of complete starting ration in his lifetime. These feed consumption rates are based upon Ralston Purina Research data.

Swine prestarter and starter rations containing .3 ppm added selenium will provide a total of 8.9 mg. of added selenium assuming a consumption of 65 pounds ration. This is an increase of 5.9 mg. consumption of added selenium over the 2.9 mg. added selenium that would be consumed by each pig consuming 65 pounds of prestarter and starter rations containing .1 ppm added selenium.

The United States annual pig crop as reported by the United States Department of Agriculture has been running about 100 million head for the past several years. If we assume each pig in the United States would be fed prestarting and starting rations containing .3 ppm added selenium, this would result in total increased consumption of 1,300 pounds added selenium. The additional 1,300 pounds selenium usage is approximately 2.7% of the estimated 21.5 metric tons of selenium currently used annually for supplementation of feed for all current approved uses. From this worst-case analysis, we can predict that the impact of our proposed use level of added selenium on the environment would be minimal.

The environments potentially impacted by this action would be copper smelters, selenium premix manufacturing sites, the feed mills where the selenium would be added, the farm areas where prestarting and starting swine are kept and fed, the areas where the resulting swine wastes are stored and/or disposed of, the soils where such waste are incorporated, and the aquatic environments into which selenium might leach from the swine wastes and/or soils where such wastes are deposited.

5. Identifications of Chemical Substances that are the Subject of the Proposed Action:

Refer to the Environmental Assessment for the Addition of Selenium to the Feed of Laying Hens, dated April 24, 1981, pages 3, 4, and 5, submitted by the American Feed Manufacturers Association, Inc. (AFMA) for this information.

6. Introduction of Substances into the Environment:

The proposed action would increase the use of elemental selenium by up to 1,300 pounds annually. In 1976, the United States chemical and pharmaceutical industries were estimated to use about 67 metric tons (15%) of the total industrial selenium consumption for that year of about 450 metric tons (United States Department of Commerce, 1978). On an annual basis, about 1/3 of this 67 metric tons (21.5 metric tons) was estimated to be used for addition to animal feeds (AFMA, 1972 and 1976). The proposed action will increase the maximum annual consumption of selenium in animal feeds by about 2.7%.

Refer to the Environmental Assessment for the Addition of Selenium to the Feed of Laying Hens, dated April 24, 1981, pages 5 through 12 submitted by AFMA for further information (attached).

7. Fate of Emitted Substances in the Environment:

Refer to the Environmental Assessment for the Addition of Selenium to the Feed of Laying Hens, dated April 24, 1981, pages 12 through 22, submitted by the AFMA, for this information (attached).

8. Environmental Effects of Released Substances:

Refer to the Environmental Assessment for the Addition of Selenium to the Feed of Laying Hens, dated April 24, 1981, pages 22 through 28, submitted by AFMA, for this information (attached).

9. Utilization of Natural and Cultural Resources and Energy:

Refer to the Environmental Assessment for the Addition of Selenium to the Feed of Laying Hens, dated April 24, 1981, pages 28 and 29, submitted by the AFMA, for this information (attached).

10. Disruption of the Physical Environment:

The nature and magnitude of this action seems unlikely to result in disruption of the physical environment as selenium is an element that will probably be reincorporated into the soil.

11. Mitigation Measures:

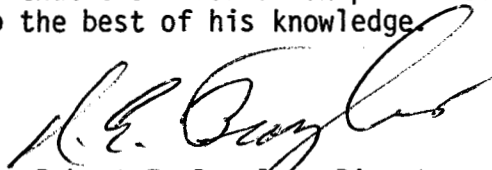
To control potential adverse effects due to over-supplementation of feeds, the FDA food additive regulation governing the use of selenium in feed stipulates that no more than one pound of a premix containing a maximum of 90.8 mg. of selenium per pound may be added to a ton of complete feed. It has been determined that 5 ppm selenium (both added and natural) is the toxic dietary selenium concentration for weanling pigs. Rations containing levels of 2.5 ppm added selenium can be fed without adverse effects. Twenty-five pounds of selenium premix containing 90.8 mg. selenium per pound would have to be added to provide 2.5 ppm added selenium. This is a practice which is not expected to occur because of physical and economical reasons.

12. Alternatives to the Proposed Action:

Refer to the Environmental Assessment for the Addition of Selenium to the Feed of Laying Hens, dated April 24, 1981, pages 29 through 34, submitted by the AFMA for this information (attached).

13. Certification:

The undersigned certifies that the information presented is true, accurate, and complete to the best of his knowledge.



Robert E. Broyles, Director
Corporate Regulatory Compliance

Environmental Assessment for the Addition of Selenium
to the Feed of Laying Hens

1. Date: April 24, 1981
2. Name of applicant/petitioner: American Feed Manufacturers Association, Inc.
3. Address: 1701 N. Ft. Myer Drive
Arlington, Virginia 22209
4. Description of the proposed action:

The American Feed Manufacturer's Association (AFMA) has petitioned the Food and Drug Administration (FDA) for recognition of the addition of up to 0.1 ppm selenium (as sodium selenite or sodium selenate) to the feed of hens (on a complete feed basis) producing eggs for human consumption. AFMA has also requested removal of the provision limiting the feeding of supplemental selenium to growing chickens less than 16 weeks of age, that replacement pullets over 16 weeks of age can also receive supplemental selenium. Selenium is an essential trace element in animal nutrition. Major areas of the U.S. and crops grown thereon are deficient in selenium content. Other areas are marginal. Supplemental selenium is required to preclude feed deficiencies, and to maintain a normal food content of selenium. The selenium status of the United States is illustrated in the selenium map of the U.S. published in the Journal of Agricultural and Food Chemistry, (Kubota, 1967).

Layers are the only major food animal not presently approved to receive supplemental selenium in their diet. Swine, turkeys, and growing chickens have received supplemental selenium since January 1974. Ewes and young lambs have received it since March 1978. Supplemental selenium for all sheep, dairy cattle, and beef cattle has been approved since January 1979. Supplemental selenium has been considered appropriate and used in feeds for non-food animals since January 1974. Direct human supplementation comparable to levels for animals has been practiced for a number of years. Only layers and minor food animals, such as ducks and rabbits, are not presently approved for selenium supplementation.

The addition of layers to the approved ranks of animals will result in only a minimal increase in total use of supplemental selenium. The potential environmental effect will likewise be relatively minimal in nature.

Assuming that all feeds for laying hens located in selenium deficient areas (AFMA 1972), were to be supplemented with selenium in the form of sodium selenite, the result would be an additional selenium use of 1.03 metric tons. Supplementation of replacement pullet feeds from 16 weeks to onset of lay would require an additional 0.06 of a metric ton of selenium. This would be a total of 1.09 metric tons - or about 1.1 metric tons of selenium. This is approximately 5% of the estimated 21.5 metric

tons of selenium already used annually for the supplementation of feed for beef and dairy cattle, sheep, swine, turkeys and growing chickens. Thus, the incremental adverse impact on the environment should be negligible. Environmental benefits of this supplementation are the greater health and productivity of laying hens receiving supplemental selenium. This recently was pointed out in the October 1980 report of the Council on Agricultural Science and Technology (CAST) entitled, "Impact of Government Regulations on Development of Chemicals Used in Animal Production," which cites the delay in the approval of supplemental selenium for laying hens and uses selenium as a case study in its Attachment 3. The CAST report expands the earlier representations and projections which have been made regarding the benefits available from selenium supplementation.

The environments potentially impacted by this action would be: copper smelters, selenium premix manufacturing sites, the feed mills where the selenium would be added, the farm areas where the layers are kept and fed, the areas where the resultant chicken wastes are stored and/or disposed of, the soils where such wastes are incorporated, and the aquatic environments into which selenium might leach from the chicken wastes and/or soils where such chicken wastes are deposited.

5. Identification of chemical substances that are the subject of the proposed action:

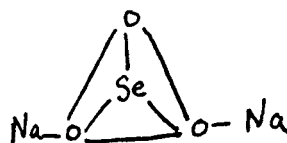
(A) Description of the substance(s):

- 1) Common or usual name - Selenium. Common names of Selenium sources are -

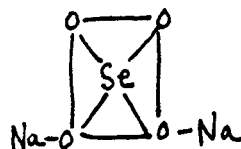
- a) Sodium Selenite, or
- b) Sodium Selenate
- 2) Chemical names (as above)
- 3) Chemical Abstract Service (CAS) registry number (NIOSH, 1978)
 - a) Sodium Selenite is 10102-18-8
 - b) Sodium Selenate is 13410-01-0
 - c) Selenium (elements) is 7782-49-2
- 4) Empirical formula, molecular weight and physical description.
 - a) Sodium Selenite - Na_2SeO_3 , 172.95, odorless white solid
 - b) Sodium Selenate - Na_2SeO_4 , 188.94, odorless white crystal

5) Structural formula -

- a) Sodium Selenite



- b) Sodium Selenate



6) Specifications for feed grade materials -

- a) Sodium Selenite - commercial grade
- b) Sodium Selenate - commercial grade

7) Typical quantitative compositions (AFMA, 1979)

	a) <u>Sodium Selenite</u>	b) <u>Sodium Selenate</u>
Purity	99.9%	99.9%
Lead	.08%	.09%
Arsenic	None	None
Mercury	.0008%	.0008%
Cadmium	.008%	None

8) Other properties (NIOSH/OSHA unpublished)

	a) <u>Sodium Selenite</u>	b) <u>Sodium Selenate</u>
Boiling Pt (760 mm Hg):	decomposes	decomposes
Specific Gravity (H ₂ O = 1) :	3.1	3.1
Melting Pt.:	710°C decomposes	decomposes
Vapor Pressure (20°C) :	<0.001 mm Hg	<0.001 mm Hg
Water solubility (20°C) :	850g/liter	415g/liter

6. Introduction of substances into the environment:

Selenium is not mined alone, but is derived as a by-product from the precious-metal-rich anode slimes obtained from the electrolytic refining of copper. Three copper refineries in the U.S. recover selenium from materials of their own and from materials of other domestic and foreign plants (U.S. Bur. Mines, 1978). These three refiners are: 1) AMAX Copper, Inc. in Cartet, N.J.; 2) ASARCO Copper, Inc. in Amarillo, Texas; and 3) Kennecott Copper Co. in Magna, Utah. In 1978, domestic refiners produced about 209 metric tons of selenium (U.S. Bur. Mines, 1979). However, this only supplied about one-third of U.S. needs and an additional 409 metric tons were imported. Selenium supplementation of layer feeds apparently can be accomplished out of existing domestic and imported production of selenium.

The proposed action would increase the use of elemental selenium by up to 1.1 metric tons/yr., or a maximum of about 2.5 metric tons/yr of sodium selenite or sodium selenate is expected to be added to the diet of laying hens (AFMA, 1972) since these compounds are approximately 45% selenium by weight.

Sodium selenite and sodium selenate are the two chemical forms of selenium approved for use as a feed additive for several species of food-producing animals. Sodium selenite appears to be widely preferred for feed use over sodium selenate, as most of the nutritional research was done using sodium selenite. Sodium selenite also has a higher selenium content, while costing about the same as sodium selenate. Sodium selenite and sodium selenate are both manufactured at three plants in New Jersey: Atomergic Chemetals Corp. in Plainview; City Chem. Corp. in Jersey City; and, Fairmont Chem. Co., Inc. in Newark (Versar, 1975).

To prepare these compounds, elemental selenium is chemically treated with concentrated nitric acid to yield selenium dioxide and selenious acid. Selenium dioxide can then be dissolved in water and neutralized with sodium hydroxide to yield sodium selenite. Selenic acid is used to form selenates. Selenic acid is formed by using powerful oxidizing agents on selenium or selenious acid (Rosenfeld and Beath, 1964).

In 1976, the U.S. chemical and pharmaceutical industries were estimated to use about 67 metric tons (15%) of the total industrial selenium consumption for that year of about 450 metric tons (U.S. Dept. Commerce, 1978). On an annual basis, about one-third of this 67 metric tons (21.5 metric tons) was estimated to be used for addition to animal feeds (AFMA, 1972 and 1976). The proposed action will increase the maximum annual consumption of selenium in animal feeds by about 1.1 metric tons to a total of about 22.6 metric tons. There is no information available in the literature on discharges from the production of selenium-containing chemicals and pharmaceuticals.

Since it represents such a relatively small incremental increase in current selenium production, the proposed action probably would have no effect upon compliance with current emission requirements at production sites. The proposed action probably would also represent a minor addition to the total current emissions from sites of production, transport, use and disposal. (All phases from production of selenium through production and use of supplemented feed). The total environmental emissions of selenium in 1976 were estimated to be over 990, 1020 and 820 metric tons into the airborne, aquatic, and solid waste routes respectively (EPA, unpublished).

The proposed action might potentially result in effects in the environments of the following human and ecosystem components.

1. Workers in copper smelters
2. Workers in chemical and pharmaceutical/premix manufacturing plants
3. Workers in feed mills
4. Workers feeding animals
5. Air
6. Water
7. Soils
8. Solid Wastes

Following are identifiable Federal limits, criteria, and/or standards for selenium in various environments.

1. NIOSH/OSHA Draft Technical Standard for occupational exposures to selenium compounds -

Permissible exposure - exposure of employees to airborne concentrations of selenium and inorganic compounds (as selenium) not in excess of 0.2 mg/m³ of air, as averaged over an eight-hour work shift.

2. Public Health Service (PHS) Mandatory Upper Limit for selenium in drinking water -

10 ppb

3. Environmental Protection Agency (EPA) Ambient Water Quality Criteria for selenium -

- a. To protect human health = 10 ppb
- b. To protect freshwater aquatic life = 35 ppb (as a 24 hr. avg., and concentration should not exceed 260 ppb at any time)

- c. To protect saltwater aquatic life = 54 ppb (as a 24 hr. avg., and concentration should not exceed 410 ppb at any time)

- 4. EPA Solid Waste Criterion for selenium levels in sludges - >1.0 ppm of extractable Se requires listing as a hazardous waste.

Environmental Exposures

In general, Americans do not appear to be exposed to excessive levels of selenium in their food, water, air, or workplace. Human selenium intake is on the order of about 0.06 to 0.15 mg/day (Beliles, 1975) with the bulk of that probably coming from their diet. Selenium enters the food chain almost entirely via plants (NAS, 1976).

Selenium concentration in plants and animals depends largely on the concentrations and availability of selenium in the soil where the plants are grown. Morris and Levander (1970) took a cross section of the American diet and found the selenium content varied from about 0.01 to 0.50 ppm (wet weight). The 1976 National Academy of Science (NAS) report on Selenium concluded that "there seems no reason to expect either inadequacy or excess of the element [selenium] in our diets. . . ." The NAS Food and Nutrition Board's Recommended Dietary Allowances (1980) sets an estimated safe and adequate intake range of

selenium for adult humans of 0.05 - 0.2 mg per day, or 50-200 ug per day. The 200 ug per day level is equivalent to the animal dietary level of 0.1 ppm. The NAS Board's Recommended Dietary Allowances further states that "Selenium intakes within the range of 50-200 ug/day can be obtained easily from a varied diet."

There are certain geographical areas which are seleniferous and produce plants with high selenium content. Certain "indicator" plants have been found to concentrate extremely high levels of organic selenium. Occasionally livestock are forced to consume these plants and have developed diseases called "blind staggers" and "alkali disease" (NAS, 1976). Acute toxicity has resulted in animals consuming plants with high selenium levels (Burk, 1976). Whether selenium is responsible for this toxicity is open to question (Van Kampen and James, 1978). In contrast, geographic areas which are selenium deficient often result in plants with low selenium levels and animals fed diets from such plants - without supplementation - do not receive enough of this essential trace element in their diet (AFMA, 1972 and 1976).

The NAS (1976) reported that surface waters rarely contained selenium at levels above a few ppb. Water from wells in seleniferous areas and river waters containing irrigation drainage of seleniferous soils were sometimes found to have higher selenium levels.

The EPA (1975) reported only one sample out of 418 analyzed for Interstate Carrier Water Supplies in 1975 exceeded the 10 ppb drinking water limit. Craun et al. (1977) tested over 3,500 home tap water samples from residences in 35 geographically dispersed areas. They found less than 10% of these samples were above the minimum detection limit of 1 ppb and that the average of the mean selenium levels detected in the 35 areas was 3.82 ppb.

Most urban regions have aerial concentrations of particulate selenium ranging from about 0.1 to 10 ng/m³ (NAS, 1976; Zoller and Reamer, 1976). The airborne levels of selenium do not contribute significantly to the overall human exposure levels (EPA, 1979). The vast majority of the selenium present in the air undoubtedly comes from the burning of coal and oil (NAS, 1976).

There is little information available on current actual exposure to selenium in the work environment. Proctor and Hughes (1978) briefly mention an older study of a selenium plant where workroom air levels ranged from 0.2 to 3.6 mg/m³. This information was not confirmed in the article cited (Glover, 1970). In 1972, the United Nations International Labor Office (ILO, 1972) stated that "there have been no deaths or cases of irreversible pathological conditions due to selenium or its compounds in industry, agriculture or medical practice." While this report describes the potential hazards of working around selenium compounds, it

also states that "selenium compounds may be safely ingested by man in concentrations which, if ingested by animals would cause acute and chronic diseases and death."

In contrast with the foregoing, there was a report from Japan found "that increasing numbers of female workers in the manufacture of selenium rectifiers had irregular menses or menostasis" (NAS, 1976). This points out that the chronic effects of occupational exposures to selenium should be further monitored and current exposure levels determined.

7. Fate of emitted substances in the environment:

This action deals specifically with the use of sodium selenite or sodium selenate in laying hen feeds. The selenites and selenates, however, can be converted and/or metabolized into other selenium compounds (Figure 1), and the fate of the major selenium compounds will be briefly considered in this section. More comprehensive reviews on selenium fate can be found in NAS (1976) and Callahan et al. (1979).

Selenium is able to exist in the natural environment in four basic forms (oxidation states); as selenides (-2 state), as elemental selenium (0 state), as selenites (+4 state), and as selenates (+6 state). Which of these forms predominates depends upon the pH and redox potential of the environment (Callahan et al. 1979).

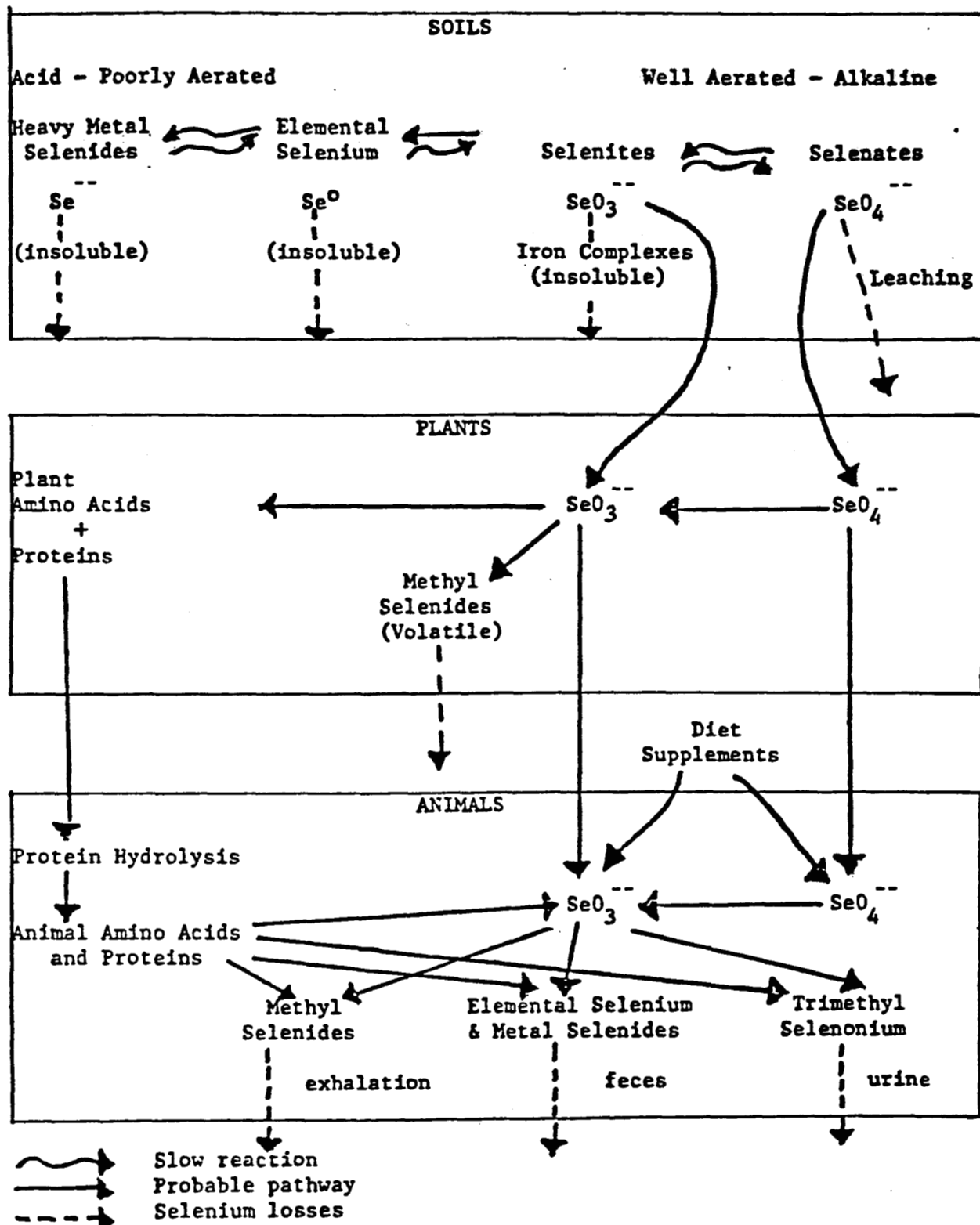


Figure 1 - Chemical and biochemical changes in selenium moving from soil through plants to animals. Adapted from NAS (1976).

Most selenides are very insoluble compounds that usually slowly decompose into elemental selenium. Elemental selenium is extremely insoluble in water, absorbs to sediments, and is generally non-toxic. These two forms of selenium are both fairly non-toxic and often end up in sediments as the major inert "sink" for selenium introduced into the environment (NAS, 1976).

Selenites are soluble in water and, in sandy soil, can be taken up by plants. However, under acidic conditions the selenites are often rapidly reduced in the environment to the relatively non-toxic and insoluble elemental selenium. Also selenites will quickly form insoluble absorbates with iron oxides. These characteristics, along with a relatively slow conversion to selenates under alkaline conditions, minimize the hazard of transport and environmental pollution by the selenites (NAS, 1976; Callahan et al., 1979).

Selenates are very soluble in water, stable at alkaline pH, and are also a readily available form for plant uptake. Soluble selenates are the form of selenium responsible for most naturally occurring instances of plants excessively accumulating selenium. These characteristics appear to make the selenates the form of selenium with the most potential for environmental pollution (Callahan et al., 1979). Fortunately, the selenates, which are usually present at lower levels and under acidic conditions, are often converted to other environmentally less dangerous forms of selenium.

When given as a dietary feed supplement to animals, sodium selenite was absorbed better from the gastrointestinal tract of monogastric animals than by ruminant animals (Wright and Bell, 1966). Such species differences are thought to be due to the reduction of the selenite to insoluble or unavailable forms by rumen microbes (NAS, 1976). When absorbed, the inorganic selenites and selenates can be metabolized and incorporated into protein materials, or may be excreted in various forms. Selenates are converted to selenites, which can be detoxified by metabolism to methyl selenides for elimination via exhalation, to elemental selenium and metal selenides for fecal excretion, and to trimethyl selenonium for urinary excretion (NAS, 1976).

The National Academy of Sciences (1976) concludes that "selenium present in fecal material apparently is not readily taken up by plants when the fecal material is applied to soil," as selenium conversion to the inert and insoluble forms is a significant feature of the soil-plant-animal system.

Microorganisms may also interact with selenium compounds in various manners. Selenite and selenate have been shown to be toxic to some yeast and bacteria, yet some microbe strains can adapt to high selenium conditions (NAS, 1976). Not only can rumen microbes degrade selenite to less toxic forms (NAS, 1976), but Chau et al. (1976) found that benthic microflora present in lake sediments could metabolize selenium compounds, including

sodium selenite and sodium selenate, by methylation to the volatile dimethyl selenide. Biomethylation and volatilization can remobilize selenium absorbed in sediments and might possibly result in significant selenium recycling (Callahan et al., 1979).

Worst Case Analysis - Soil, no leaching

The proposed action involves an annual feeding of a maximum of approximately 1.1 metric tons of supplemental selenium to laying hens and to replacement pullets over 16 weeks of age. This would result, if none of the selenium was retained or transmitted to eggs, in 1.1 metric tons of additional selenium being excreted into the fecal matter produced by these birds. Laying hens would account for most of the selenium, slightly over one metric ton. The manure will total some 4.85 million tons, or 4.40 million metric tons (AFMA, 1972).

The AFMA (1972) expected the average selenium concentrations in the wastes of selenium supplemented animals to be about 0.25 ppm. For a two week period, Latshaw and Osman (1975) fed laying hens a diet supplemented with 0.1 ppm of sodium selenate. The hens retained 68% of the selenium in the diet and the feces of these hens contained about 0.25 ppm of selenium. The forms of selenium present in the feces were not determined.

Based on the foregoing information, a metric ton of dry chicken waste from supplemented chickens may be expected to contain about 0.25 grams of selenium. Chicken droppings are expected to be added as a fertilizer to soil at a maximum practical application rate of about 4.6 metric tons/acre. This practice would add to the soil about 1.14 grams of selenium per acre (AFMA, 1972). Under normal farming practices, this chicken waste would be incorporated into the top six inches of soil. As this six inches of soil is estimated to weigh 909 metric tons (AFMA, 1972), the 1.14 g/acre of added selenium is equivalent to an increase in soil selenium content of 1.25 ppb.

The soils in selenium deficient areas are reported to contain 40 ppb selenium or less, and areas of moderate selenium content contain from 500 to 5,000 ppb of selenium (Allaway, 1968). Therefore the addition of these chicken wastes to selenium deficient soils could increase selenium levels by about 3%/yr, and could result in a small increase in soils already containing moderate levels of selenium. Addition of selenium to the deficient soils might have a beneficial impact by increasing the selenium levels in the crops grown in these regions.

In general, farmers apply animal wastes to the soil at the time of plowing in either spring or fall. Thus, as much as one year's production of waste could be stored in piles. However, laying hens are typically raised in totally housed systems and often

their manure will be allowed to accumulate indoors for a year or longer before the housing is cleaned and addition to soil occurs (White and Forster, 1978).

Worst case analysis - Water, complete leaching from soil

The area of the U.S. which will require selenium supplementation due to deficient levels in grains and feedstuffs comprises the eastern U.S. and west coast area of California, Oregon and Washington. The eastern U.S. is defined as the area east of the western borders of the following states: Minnesota, Iowa, Missouri, Arkansas and Louisiana. Of the states in the above described deficient areas, California has the lowest mean annual rainfall of 24 inches (Miller, 1973). Twenty-four inches of rainfall would be equivalent to 2,467,051 kilograms of water per acre (AFMA, 1972). Therefore, if the amount of selenium added by a maximum of 4.6 metric tons of dry layer waste (1.14 grams) is assumed to be totally leached out of the soil by the 24 inches of rainfall (2,467,051 kilograms), the result would be a selenium concentration of 0.46 ppb in the water. The average concentration of selenium for the waters of the entire area would be lower than this figure since the average rainfall of the other states is greater than California's and thus there would be further dilution. There would be additional dilution by rainfall and runoff from other areas not amended with selenium-containing wastes.

Bioaccumulation

Except for the few selenium accumulator plant species in specific seleniferous areas, the ability of selenium to bioaccumulate in the environment seems relatively small. Callahan et al. (1979) reviewed the aquatic literature and concluded that "the small amount of available data suggest that while dietary selenium is the most important source of selenium to many marine and freshwater organisms, little biomagnification takes place." Similarly, Cardwell et al. (1979) reviewed the aquatic literature and also suggested dietary pathways were more important than aqueous pathways in selenium bioaccumulation in aquatic organisms. Cardwell et al. (1979) also mentioned that relative to the heavy metals, field studies suggested that selenium accumulative potential was low.

The National Academy of Sciences report on selenium (1976) found that when animals were exposed to increasing amounts of selenium, the tissue levels of selenium tended to plateau with selenium being excreted faster at higher dose levels. This report concluded that "when animals are supplemented with nutritional amounts of inorganic selenium, there is little or no tendency for selenium to accumulate in the edible tissues of the animals above the levels that are known to occur in animals fed diets containing adequate quantities of naturally occurring selenium."

The FDA's concern about the environmental fate and bioaccumulation potential of animal feed additives containing selenium led to a contract (FDA Contract 223-74-8251) with Dr. Robert Metcalf (Univ. Illinois) to study the fate and bioaccumulation potential of sodium selenite in model ecosystems (Metcalf, 1976).

The model ecosystems were 10 gallon aquaria containing a terrestrial component of sand with sorghum growing in it, with the terrestrial part grading into an aquatic component of water containing algae, daphnia, snails, mosquito larvae and fish.

There were two selenium studies performed under this contract. In the first study, baby chickens were kept caged above the terrestrial part and given diets supplemented with 0.1 ppm of radioactively labeled sodium selenite. The labeled selenium was readily excreted from the chicks and entered the terrestrial and water phases of the model ecosystems. Some selenium was mobilized from the soil and water into the plants and animals, with plants storing relatively more selenium. Metcalf concluded however, that the data collected did not suggest any selenium food chain build up.

Using the same type of model ecosystems, but without using chickens, Dr. Metcalf performed a second study which compared the mobilization of radiolabeled sodium selenite from the terrestrial portions of model ecosystems containing sand or

sand amended with a silty clay loam soil. One ppb of sodium selenite was incorporated into the terrestrial part of the respective model ecosystems. The terrestrial portion of the model ecosystem with soil bound the sodium selenite much more tightly than did the terrestrial portion of the model ecosystem with sand only. Nevertheless, labeled selenium was mobilized from each system and some selenium accumulated in the biota of both model ecosystems.

Metcalf (1976) concluded that no food chain build up was seen, but he nevertheless speculated that sodium selenite "appears as a potentially dangerous environmental pollutant because it was readily excreted by animals" and was mobilized from soil and water into the plants and animals of his model ecosystems.

In contrast to Metcalf's speculation about potential pollution, the NAS report on selenium (1976) concluded that selenium use is probably not a significant pollution problem as only relatively small amounts of this element are introduced into the ecosphere, and this report also said that "the projected use of selenium as an animal feed additive is considered to have little potential for contributing to the burden of this element in the environment."

These two diverse points of view illustrate that even though the use of selenium as a feed additive is justifiable from a

nutritional viewpoint and in a broad (i.e. nationwide) context, potential local effects may be more pertinent to environmental assessment of this action. A consideration of both points of view seems appropriate, yet accurate information is often lacking on the environmental effects in the locations directly impacted by the proposed (and related) actions.

8. Environmental effects of released substances:

In acute tests, sodium selenite and sodium selenate are highly toxic at low doses. The amounts of these selenium compounds required to satisfy essential nutritional requirements for selenium, however, are only between one-tenth and one-hundredth the minimum toxic levels for animals (NAS, 1976), providing a safety factor of 10 to 100 fold. No significant adverse environmental effects are anticipated when animal waste containing selenium is incorporated into the soil at a rate of 4.6 metric tons or less per acre. Precautions should be taken in those instances where animal waste is stored in piles to ensure that the selenium leached by rainfall will not have direct access to the water table or other aquatic sources. Such storage, however, is not a common practice for layer waste. Adverse environmental impact in the form of increased selenium levels in the soil and water supply might occur if animal feeds were over-formulated by the addition of excess selenium or the addition of selenium to feeds already high in selenium.

The use of selenium as a feed additive should be carefully controlled to prevent harm to either the target animals or the environment. The FDA regulations on selenium supplementation of animal feeds were written in a fashion to reduce the possibility of this occurring (FDA, 1974).

1. Toxicology

a. Animal

The chronic and acute toxicities of various forms of selenium to laboratory animals and livestock have been reviewed previously (AFMA, 1972; NAS, 1976; Fishbein, 1977; EPA, 1979). Many factors enter into selenium toxicity, such as: (1) size and frequency of the doses; (2) characteristics of the compound; (3) presence of combining, reducing, diluting, or synergistic substances; (4) inherent susceptibility of the animal; and (5) efficiency of elimination after absorption (Muth and Binns, 1964).

The amount of supplemental selenium required to satisfy essential nutritional requirements of laying hens, which is 0.1 ppm, is about one-thirtieth of the minimum toxic level of about 3 ppm. Supplemental selenium for laying hens thus has a safety factor comparable to other micronutrients.

A variety of toxic effects are noted when excessive quantities (3-5 ppm over a sustained period) of selenium are ingested by livestock and poultry. Generally, these animals will suffer

from a loss of appetite, atrophy of the heart, cirrhosis of the liver and anemia.

In seleniferous areas, diets containing 5 ppm or more of selenium have been accepted as the dividing line between toxic and nontoxic feeds (NAS, 1976). Chronic selenium toxicity in livestock occurs when animals consume seleniferous plants containing 5-20 ppm of selenium over a prolonged period. Consumption of plant materials containing 400-800 ppm of organic selenium has been acutely fatal to sheep, hogs, and calves.

Toxic effects (up to and including lethality) of selenium can appear in livestock and chickens at dose levels of about 3-10 ppm in feed (AFMA, 1972; FDA, 1974; NAS, 1976; Fishbein, 1977; EPA, 1979). Therefore normal feeds (approximately 0.05-0.1 ppm selenium) that have in addition been supplemented with 0.1 ppm of selenium from sodium selenite or sodium selenate have a safety margin of about 20 to 50X for poultry and livestock. The fact that selenium from sodium selenite and sodium selenate is so toxic at high levels results in an environmentally beneficial side effect. If animals are accidentally over-dosed with selenium from either compound, the effects would be readily evident before significant quantities of selenium might be released or mobilized into the environment.

b. Human

Available animal data which have been extrapolated to effects on humans have been evaluated by the National Cancer Institute and the Food and Drug Administration (FDA, 1974). These data are summarized as follows: Selenium at high dietary levels (above 2 ppm) is a proven hepatotoxic agent. The evidence for carcinogenic effects at higher levels is inconclusive, but selenium at the nutritionally required levels was concluded not to be carcinogenic. In fact, recent evidence suggests that selenium may even be anticarcinogenic (NAS, 1976; Fishbein, 1977; EPA, 1979; Greeder and Milner, 1980).

Information concerning the potential toxicity of selenium in human diets in the United States has been collected and summarized by Smith and Westfall (1937), Williams et al. (1941), Trelease and Beath (1949), Hadjimarkos (1965), Frost (1972) and the National Academy of Sciences (1976). A review of these citations reveals no evidence that any people in the U.S. are exhibiting effects of toxic levels of selenium in food. Several investigators have provided evidence that elevated dietary selenium-levels may contribute to increases in dental caries (Hadjimarkos, 1965; Ludwig and Bibby, 1969; Buttner, 1963).

Public Health officials took action on the basis of reports that selenium may contribute to dental caries, on reports that the element is a potential carcinogen, and that concentrations of selenium in water considered safe for man were found toxic for fish. Their action took the form of lowering the previous standard for selenium in water from 50 ppb to 10 ppb (PHS, 1962).

c. Other Biota in the Environment

It is well-known that certain native plants growing on seleniferous soils accumulate high concentrations of selenium (Rosenfeld and Beath, 1964). In certain locations, accumulator species containing over 1,000 ppm of selenium have been found growing alongside grasses containing less than 10 ppm. These so-called selenium accumulator plants include 24 species and varieties of Astragalus (milk vetch); section Xylorhiza (woody aster) of Machaeranthera; section Oonopsis (goldenweed) of Haplopappus; and Stanleya (prince's plume). The accumulator plants generally grow in dry, nonagricultural areas which are unlikely to be fertilized with poultry manure, and range animals do not graze these areas unless forced to by a shortage of other feed.

Information with regard to the wildlife which feed on selenium accumulator plants is unavailable. Since these are noxious weeds which contain high levels of selenium, it is unlikely

that these plants would be preferred as a feed source for the indigenous fauna. Probably, the toxicity of selenium to wild herbivores would be of the same order of magnitude as that observed in domestic livestock and poultry.

Based upon the toxicity information and the estimates of selenium maximally entering the environment, the proposed action is unlikely to result in the mobilization of significant quantities of selenium for uptake by plants, and were this to happen in the anticipated selenium deficient areas, it would probably be beneficial.

Water supplies, even in seleniferous areas of the western U.S., have not been considered a potential source of human toxicity (EPA, 1979). The toxic effects of selenium on the aquatic biota have been reviewed by Rosenfeld and Beath (1964), FDA (1974), Metcalf (1976), EPA (1976 and 1979) and Cardwell et al. (1979). In the aquatic species tested, sodium selenite and sodium selenate in water were acutely to chronically toxic at concentrations ranging from approximately 2.5-10 ppm (or less), with some aquatic invertebrates and algae more sensitive than fish. In 1976, the EPA water quality criteria for selenium were set at 10 ppb for domestic water supplies (human health) and for marine and freshwater aquatic life at 1% of the 96-hour LC₅₀ through bioassay of a sensitive resident species (EPA, 1976). These criteria were criticized as being

unsupported and too lenient by Cardwell et al. (1979). Based upon information that selenium can be accumulated to toxic concentrations by trophic levels below fish and that ingested selenium can kill fish at low concentrations, Cardwell et al. (1979) suggested water criteria of 0.1% of the 96-hour LC₅₀ and a maximum selenium total water concentration of 50 ppb. The final EPA ambient water quality criteria for selenium (EPA, 1980) reviewed the literature and while it does not change the criterion for human health, the aquatic life criteria were changed. The criterion suggested to protect freshwater life is 35 ppb as a 24-hour average and is never to exceed 260 ppb. The suggested criterion to protect saltwater aquatic life is 54 ppb as a 24-hour average and should not exceed 410 ppb at any time.

Based upon the worst case analysis for leaching and the general lack of bioaccumulation ability of selenium, the proposed action seems unlikely to result in a situation where these criteria in water should be approached, let alone exceeded.

9. Utilization of natural and cultural resources and energy:

The energy required to produce 1 net ton of selenium powder is estimated to equal 297 million Btu (U.S. Bur. Mines, 1978). The proposed action is roughly estimated to increase current uses of selenium by up to 1.1 metric tons. This is a fraction of the 618 metric tons of selenium already used annually in the

U.S., two-thirds of which is imported (U.S. Bur. Mines, 1979). Therefore the impact upon utilization of natural and cultural resources and energy in the U.S. should be expected to be minimal.

10. Disruptions of the physical environment:

The nature and magnitude of this action seems unlikely to result in disruption of the physical environment as selenium is an element that will probably be reincorporated into the soil.

11. Mitigation measures:

To control potential adverse effects due to over-supplementation of feeds, the FDA food additive regulation governing selenium use in feeds stipulates that no more than one pound of a premix containing a maximum of 90.8 mg of selenium per pound may be added to a ton of complete type feed. At this premix concentration, 30 pounds of premix would have to be added to a ton of feed to reach a selenium level potentially toxic to chickens, a practice which is not expected to occur.

12. Alternatives to the proposed action:

Adverse environmental effects are not expected as a result of the proposed action and therefore alternatives to the action

need not be considered. Nevertheless, a description of possible alternatives will illustrate a need for the proposed action and practical approaches in implementing it.

The most practical method for correcting or preventing a selenium deficiency in poultry and livestock is the direct administration of supplemental selenium to the animals through their feed. Two potential problems are pertinent in evaluating the feed route as a means of administering physiologically effective quantities of selenium. The amounts required are so small (less than 1 ppm in the diet dry matter) that there can be a practical problem of adequate mixing with the large mass of feed material, and there is the possibility of over-formulation. These problems should be considered in any program of direct addition of selenium to animal feed. They were addressed in the provisions of the Food Additive Regulation for selenium which limits the potency of selenium premixes and the quantity of premix to be added to a ton of feed.

The alternative of not permitting the use of selenium would force livestock producers to rely on selenium obtained from natural sources. This alternative has been rejected since natural sources (feedstuffs and drinking water) often contain less than the needed amount of selenium. In 1972, the AFMA estimated a total annual loss to pullet and egg producers of \$6.87 million because selenium was not used to supplement the diets of these birds.

There are several alternative ways in which selenium administration could be accomplished.

A. Soil Amendment

Selenium can be added to the soil on which our basic feedstuffs are grown. This practice has been successful in New Zealand since the 1960's, where farmers have applied 14-28g of selenium (as sodium selenite) per acre. Since the selenium-deficient arable area of the U.S. encompasses in excess of 509 million acres, this technique of selenium treatment would require the distribution of at least 7,000 metric tons of selenium. The entire proposed animal feed uses of selenium would involve only approximately 22.6 metric tons. From an environmental standpoint, therefore, dietary uses are more desirable, as that approach results in decreased energy uses and reduced distribution of selenium broadcast into the environment.

B. Interregional Feed Blending

Certain areas of the country produce basal feedstuffs which contain quantities of selenium at or above the required levels. Feedstuffs high in selenium content could be blended with those low in selenium to produce feedstuffs with adequate levels of selenium. This alternative has the advantage of not resulting in additional selenium introductions into the environment. There are several practical disadvantages to this alternative, 1) there probably are insufficient quantities of high selenium ingredients

to adequately balance the low selenium ingredients, 2) high selenium commodities would have to be identified and kept segregated in the marketplace, and 3) the extra costs (energy, etc.) associated with handling and transporting additional separate categories of bulky feed ingredients around the country would probably outweigh the intended economic benefit.

C. Corporeal Injection

This process would involve injecting animals with therapeutic levels of selenium. Its disadvantages accrue from the fact that each animal would have to be handled at periodic intervals and this would be a time consuming and costly procedure. As layers and pullets are of little individual value, economic reasons counteract any benefits and make this an infeasible alternative.

D. Feed Monitoring

This alternative would provide for the establishment of a program for monitoring the levels of selenium in the animal's diet through extensive and frequent chemical or physical analyses. Analytical methods that would be required for it are available. There are several acceptable methods published in the Journal of the Association of Official Analytical Chemists (A.O.A.C.). Several methods have been developed, including x-ray fluorescence spectrometry for the detection of potentially toxic levels of selenium and procedures for determining selenium in biological materials by neutron activation analysis.

Variations of this program would require individual feedmills to analyze either each ton of feed or each lot of feed ingredients prior to the addition of selenium. If each ton of feed were analyzed (maximum analysis costs \$15-20 per sample), the analytical cost of the program alone would be a minimum of \$170-228 million dollars (about 11 1/2 million tons of feed affected), a sum which probably would exceed the potential benefit. Furthermore, since most feed mills do not have the required laboratory facilities, outside laboratories would need to be utilized. This would add a burdensome time factor.

Conclusion: Of the four alternative methods discussed as satisfying the selenium requirements of laying hens, corporeal injection would involve the environmental distribution and use of about the same quantity of selenium as the proposed action. Rejection of corporeal injection was based on feasibility and cost considerations. The additional alternative of feed monitoring which could potentially limit selenium distribution was also rejected for excessive costs. The alternative of soil amendment was rejected since its application would require additional costs as well as the use of at least 300 times more selenium than that required by feed administration. (from 7,126 to 14,252 metric tons vs. 22.6 metric tons.) The alternative of inter-regional feed blending might be considered attractive

from an environmental viewpoint since no selenium salts would have to be distributed into the environment. However, the expansion of facilities and energy consumption required to accomplish the handling and movement of additional separate categories of feedstuffs would outweigh the proposed environmental benefits.

13. List of preparers:

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Lee H. Boyd, the joint preparer, has served on the AFMA staff since 1960, with responsibilities for technical-scientific matters and regulatory compliance activities. Prior to joining AFMA, he had similar responsibilities for seven years with a midwest feed manufacturing firm. He received a B.A. in general science from Penn State in 1947, a B.S. in agriculture from Purdue in 1953, and a J.D. degree from Catholic University in 1979.

Mr. Boyd prepared the original petitions for selenium supplementation of animal feeds resulting in approval for swine, turkeys, and growing chickens. He was a member of the task force preparing subsequent petitions securing approval for sheep and for dairy and beef cattle. He is also the preparer of the pending petition for layers.

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14. Certification:

The undersigned certifies that the information presented is true, accurate, and complete to the best of his knowledge.

This 24th day of
April, 1981

Signature of responsible official

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